

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Tesfaye Biftu, et al

Serial No. 10/556,805

Filed: November 14, 2005

For: 3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES
AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE
TREATMENT OR PREVENTION OF DIABETES

Art Unit: _____

Examiner: _____

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

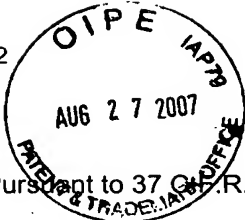
Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Pamela Spaulding Date 8-24-07



INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

| RELATED APPLICATION | | |
|---------------------|-------------|------------|
| U. S. SERIAL NUMBER | FILING DATE | MERCK CASE |
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If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: Philippe L. Durette

Attorney _____ For Applicant(s)

Reg. No. 35,125 _____

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-4568 _____

Date: August 24, 2007 _____

COMPLETE IF KNOWN

(use ~~as~~ many sheets as necessary)

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|-----------------------------|----------------------|
| Application Number | 10/556,805 |
| Filing Date | November 14, 2005 |
| First Named Inventor | Tesfaye Biftu, et al |
| Group Art Unit | |
| Examiner Name | |

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Attorney Docket Number 21404P

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| Examiner Initials* | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY |
|--------------------|----------|-------------------------|-----------------|-------------------------|--|---|
| | | Office | Number | Kind Code (if known) | | |
| | 1 | PCT | WO 97/40832 | | Hans-Knoll-Institut Fur Naturstoff-Forschung E. V. | 11/06/1997 |
| | 2 | PCT | WO 98/19998 | | Novartis AG | 05/14/1998 |
| | 3 | PCT | WO 00/34241 | | Novartis AG | 06/15/2000 |
| | 4 | PCT | WO 01/34594 A1 | | Guilford Pharmaceuticals, Inc. | 05/17/2001 |
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Date
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| Sheet | 2 | of | 4 | Attorney Docket Number | 21404P |
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| Examiner Initials* | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY |
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

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| Examiner Name | |
| Attorney Docket Number | 21404P |

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| Sheet | 3 | of | 4 |
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY |
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| | | Office | Number | Kind Code (if known) | | |
| | 21 | PCT | WO 2005/011581 A2 | | Merck & Co., Inc. | 02/10/2005 |
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Examiner
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Considered

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| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | COMPLETE IF KNOWN | | |
| | | | Application Number | 10/556,805 | |
| | | | Filing Date | November 14, 2005 | |
| | | | First Named Inventor | Tesfaye Biftu, et al | |
| | | | Group Art Unit | | |
| | | | Examiner Name | | |
| Sheet | 4 | of | 4 | Attorney Docket Number | 21404P |

| NON PATENT LITERATURE DOCUMENTS | | |
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| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
| | 1 | Augustyns, K. et al., "Dipeptidyl peptidase IV inhibitors as new therapeutic agents for the treatment of Type 2 diabetes" Expert Opin. Ther. Patents, Vol. 13, No. 4, pp 499-510, 2003 |
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| | 3 | Deacon, C. F., "Perspectives in Diabetes - Therapeutic Strategies Based on Glucagon-Like Peptide 1" Diabetes, Vol. 53, pp 2181-2189, 2004 |
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| | 7 | Knudsen, L. B., "Glucagon-like Peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes" J. Med. Chem, Vol. 47, pp 4128-4134, 2004 |
| | 8 | Novartis AG: WO0034241 - "Novel N-substituted-2-cyanopyrrolidines as potent inhibitors of dipeptidyl peptidase IV in the treatment of non-insulin-dependent diabetes mellitus", Exp. Opin. Ther. Patents, Vol. 10, No. 12, pp 1937-1942, 2000 |
| | 9 | Vahl, T. P. et al., "Gut peptides in the treatment of diabetes mellitus", Expert Opin. Investig. Drugs, Vol. 13, No. 3, pp 177-188, 2004 |
| | 10 | Holst, J. J. et al., "Glucagon-like peptide 1 and inhibitors of dipeptidyl peptidase IV in the treatment of type 2 diabetes mellitus" Current Opinion in Pharmacology, Vol. 4, pp 589-596, 2004 |
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